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EXAMINER

QUAN, ELIZABETH S

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,523

Applicant(s)

BERGER ET AL.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. Applicant claims that a copy of a European Search Report has been submitted with the Information Disclosure Statement filed 5/15/2003. However, only prior art has been submitted with the Information Disclosure Statement filed 5/15/2003. Applicant is encouraged to submit the European Search Report as stipulated on the Information Disclosure Statement filed 5/15/2003.

3. The information disclosure statement filed 5/15/2003 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

This pertains to German prior art with document number 29823595.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Referring to claim 10, it is unclear how "uniform" characterizes the docking stations and docking sites.

7. Claim 19 provides for the use of the analyzing system, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

8. Referring to claims 22 and 24, it is unclear what the different between the systems are.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-11, 13-15, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0252 631 to Lillig et al.

Referring to claims 1-11, 13-15, 19, Lillig et al. disclose an analyzing system (127) for analyzing medical samples (see FIGS. 1-5; ABSTRACT). Since patient samples are being analyzed, body fluids are analyzed. The system is suitable for use in hospitals and commercial

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laboratories (see COL. 1, lines 4-7). The system (127) comprises of analysis modules (24-30,34) within modular analyzer (10) and analysis means (80-84) within modular analyzer (60) (see FIGS. 1-5; COL. 3, lines 30-56; COL. 4, lines 1-43; COL. 5, lines 5-50; CLAIM 1). Analysis modules (24-30,34) may be similar to various modules included in the ASTRA Analyzer from Beckman Instruments, Inc. of Brea, California (see COL. 3, lines 45-56; COL. 4, line 1). Analysis module (34) is capable of analyzing electrolytes, including chloride, sodium, potassium, and carbon dioxide (see COL. 3, lines 49-56; COL. 4, line 1). The work surface of modular analyzer (10) is supported by a frame (42), which supports an electronics card cage (44), which includes a plurality of circuit boards (46), disk drive (47), and related electronic circuitry for controlling the modular analyzer (10) (see COL. 4, lines 10-15). A computer terminal, including a keyboard and printer, are connected to the electronic circuitry of the card cage (44) for providing instructions to and receiving results from the modular analyzer (10) (see COL. 4, lines 17-23). The modular analyzer (60) includes a card cage (114), which holds a disk drive (115) and plurality of circuit boards containing the control and analysis electronics of modular analyzer (60) (see COL. 6, lines 47-50). A computer terminal, including a keyboard and printer, are connected to the control and analysis electronics for providing test and operating instructions to the modular analyzer (60) (see COL. 6, lines 50-55). The modular analyzers (10,60) may be operated independently to perform clinical chemistry tests, addressing certain distinct capacity, menu and throughput capabilities needed in clinical chemistry laboratories in one position (see COL. 7, lines 44-48). The modular analyzers (10,60) may be joined to form a single clinical chemistry system (127), possessing the attributes of both analyzers (10,60) while significantly decreasing operator workload and involvement as compared to two separate

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analyzers in another position (see FIG. 3; COL. 7, lines 48-58; COL. 8, lines 1-17). The modular analyzers (10,60) are joined by placing spacers (136) between holes (50) and (118), retaining them by bolts (138) and nuts (140), and inserting locating pins (142) into the holes (56,58,124,126) within the corresponding index plates (52,54,120,122) (see COL. 8, lines 2-8).

A false panel (143) is installed between the modular analyzers (10,60) to maintain separate cooling airflow within the respective modular analyzers (10,60) (see COL. 8, lines 8-11). When the modular analyzers (10,60) are joined, electronic, electrical, and fluid interfaces are also provided between the analyzers (10,60) to form the system (127) (see FIGS. 3-5; COL. 8, lines 33-35). It appears that the docking stations and sites are of uniform type, such that electronic, electrical, and fluid interfaces can be formed between the analyzers. Interface circuit cards (144) and (146) are installed into the card cages (44) and (114) and suitable cabling (147) is connected therebetween (see COL. 8, lines 35-38). It appears that sockets receiving the cabling between the modular analyzers (10,60) would be inherent, as there is a need for the cabling to be received in something. Interface card (146) provides program, data, and timing signals vial cabling (147) to the card (144) (see COL. 8, lines 41-43). Operating software for one or more microprocessors in the modular analyzer (10) may be loaded from the disk drive (115) through the interface cards (146) and (144) to suitable memory means within the modular analyzer (10) (see COL. 8, line 56; COL. 9, lines 1-4). The cards (144) and (146) allow the results of tests performed by the modular analyzer (10) to be relayed to the modular analyzer (60), such that the results are combined with results produced by the modular analyzer (60) and displayed on the terminal or printed on the printer connected to the modular analyzer (60) (see COL. 9, lines 5-12). Because all test identification and operational control for the system (127) is made via the terminal and

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printer connected to the modular analyzer (60), the terminal and printer connected to the modular analyzer (10) may be removed (see COL. 9, lines 12-16). The modular analyzers (10,60) may both include the same microcomputer bus structure that is interconnected by the interface cards (144) and (146), such that software, operating information and instructions, test results, and timing and clear signals may be transferred between the microcomputer bus in each of the modular analyzers via the interface cards (144,146) (see COL. 9, lines 46-50). It appears that an energy supply bus is provided within the bus system since energy is required to operate the bus system. Since the bus system operates to control the transfer of sample between the analyzers, it appears that there is a sample bus for exchange of sample fluids. Since Applicant has not provided a working definition of a bus, Examiner has used Merriam-Webster's definition, which defines bus as a set of parallel conductors in a computer system that forms a main transmission path, in light of the prior art, which appears to describe "bus" as signal transmission lines. A sample, data, fluid, or energy bus is a signal transmission lines within an electronic structure dictating instructions on handling sample, data, fluid, or energy, respectively. The control and analysis electronics in the modular analyzer (60) may also directly access the microcomputer bus within the modular analyzer (10) for the transfer of data or instructions (see COL. 9, lines 54 and 55; COL. 10, lines 1-4). The modular analyzer (60) provides instructions to control and maintain the analyzers. The modular analyzers (10,60) share a common source of wash fluid in the system (127) (see COL. 10, lines 5-7). Concentrated wash solution from a reservoir (148) is supplied to a valve (149) and deionized water from a suitable source is applied to a similar solenoid valve (150) (see COL. 10, lines 7-10). The outputs of the valves are connected at a T connection to a solenoid controlled diverter valve (151), which either supplies diluted wash

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solution to a reservoir or supply tank (152) in the modular analyzer (10) or to reservoirs or supply tanks (154,156) in the modular analyzer (60) (see COL. 10, lines 10-15). A fluid sensor (158) senses the level of wash fluid in the reservoir (152) (see COL. 10, lines 15 and 16). The sensor is connected through false panel (143) via connector (160) to a bus carrying signals from level sensors (160,162,164) on each of the reservoirs (148,154,156) (see COL. 10, lines 17-20). The signals from the sensors (158-164) are applied to the control electronics in the card cage (114), and in response, the control electronics control valves (149-151) to replenish diluted wash solution in the reservoirs (154-158) (see COL. 10, lines 20-25). A wash fluid drain line (168) is connected from the modular analyzer (10) through the false panel (143) into a drain reservoir (170), which holes used wash fluid from the modular analyzer (60) (see COL. 10, lines 26-29).

It is noted that claim 1 is subject to a reasonably broad interpretation of at least one single analyzer in which there could be only one single analyzer for examining purposes. It is noted that the system of Lillig et al. has analyzers within analyzers. The analysis modules (24-30,34) of the modular analyzer (10), the totality of the modular analyzer (10) including the analysis modules (24-30,34), analysis means (80-84) of the modular analyzer (60), or the totality of the modular analyzer (60) including the analysis means (80-84) could be interpreted as the single analyzer(s) coupled to the computer terminal associated with either modular analyzer (10,60). The totality of the modular analyzer (10,60) along with its associated computer terminal; or each of the modular analyzers (10,60) may also be interpreted as the single analyzers coupled to either computer terminal associated with the modular analyzers (10,60). For examining purposes, the modular analyzer (60) has been interpreted as the computer-supported central unit with analyzing

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means (80-84), such that either the analysis modules (24-30,34) or the totality of the analyzer (10) along with the analysis modules (24-30,34) may be the single analyzer(s).

Referring to claim 2, the recitation of using the analyzers in a first and second positions, wherein the second position is a bedside measuring position is method limitation that is accorded no patentable weight in an apparatus claim.

Therefore, Lillig et al. include all the limitations in claims 1-11, 13-15, 19.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 2, 6, 7, 16-18, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0252 631 to Lillig et al.

Referring to claim 2, Lillig et al. do not explicitly disclose that the measuring position is a bedside measuring position. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Lillig et al. to use the analyzer in a bedside measuring position if the patient is bedridden and analysis of blood gases is necessary to diagnose the patient's condition.

Referring to claims 6 and 7, in the event one would argue that sample and energy buses are not signal transmission lines but actual lines for physically providing sample or energy, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Lillig et al. to provide the energy and sample buses to efficiently provide energy and sample buses between analyzers without having to individually provide them.

Referring to claims 16-18, Lillig et al. do not explicitly disclose the central unit with a connection for remote data transmission, such as intranet or internet connection. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Lillig et al. to provide the central unit with a connection for remote data transmission, such as intranet or internet connection, as it is well known to communicate within the organization in a secure manner through intranet or communication with other organizations or look up pertinent information through internet.

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Referring to claims 25, 26, Lillig et al. do not explicitly disclose the analyzer and central unit with transmitter/receiver systems for wireless data transfer effected by wireless technology in the 2.4 GHz range using a license-free ISM band. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Lillig et al. to provide the analyzer and central unit with transmitter/receiver systems for wireless data transfer effected by wireless technology in the 2.4 GHz range using a license-free ISM band, which is commercially available and avoids the use disorganized wires, making the analyzers more portable.

15. Claims 12, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0252 631 to Lillig et al. in view of U.S. Patent No. 5,631,844 to Margrey et al.

Referring to claim 12, Lillig et al. does not specify what type of patient sample is being analyzed for electrolytes. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Lillig et al. to analyze blood gases for electrolytes as in Margrey et al. as they are very well known and helpful in medical diagnoses as taught by Margrey et al. (see COL. 5, lines 20-25).

Referring to claims 16-18, Lillig et al. do not explicitly disclose the central unit with a connection for remote data transmission, such as intranet or internet connection. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Lillig et al. to provide the central unit with a connection for remote data transmission, such as intranet or internet connection, as it is well known to communicate within the organization in a secure manner through intranet or communication with

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other organizations or look up pertinent information through internet as taught by Margrey et al. (see COLS. 4-9).

16. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0252 631 to Lillig et al. in view of U.S. Patent No. 6,249,774 to Roden et al. or U.S. Patent No. 4,737,910 to Kimbrow.

Referring to claims 20 and 21, Lillig et al. do not explicitly disclose the claimed inventory management system in the central unit. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the central unit of the analyzer of Lillig et al. to provide the claimed inventory management system, as it is very well known, commercially available, and advantageous to prevent depleting of supplies and materials for performing analysis as taught by Roden et al. or Kimbrow.

17. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0252 631 to Lillig et al. in view of U.S. Patent No. 5,614,415 to Markin.

Referring to claims 22-24, Lillig et al. disclose that the analyzers are suitable for use in hospital and commercial laboratories. Lillig et al. do not explicitly disclose that the central unit is provided with a data link to a laboratory system, laboratory information system, or hospital information system. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Lillig et al. to provide the central unit with a data link to a laboratory system, laboratory information system, or hospital information system for rapid and efficient reporting of tests results and improving laboratory quality and efficiency since there is operation and data overlap between the hospital and laboratory as taught by Markin (see COLS. 1-5).

Double Patenting

18. Claims 1-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-26 of Application No. 09/854560. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims Application No. 09/854,560 are combination claims including all the limitations of claims 1-26 of this application.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

eq


Jill Warden
Supervisory Patent Examiner
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